

35 U.S.C. § 112, first paragraph

The specification was objected to under U.S.C. § 112, first paragraph, for the incomplete entry of the status of related applications, and for failure to include the title of this section. Applicants' have amended the specification to include the information requested.

The specification was also found objectionable regarding the use of the term BMP. Those skilled in the art would recognize that this term is an abbreviation of the term "bone morphogenic protein" which is discussed in the specification at page 3, paragraph 3. Applicants' have amended the specification to clarify any ambiguity.

The figures were found to be unacceptable in that the Examiner was unable to determine the location of "arrow 30". Applicants respectfully point out that "arrow 30" may be found in figure 1B (large arrow, in bold).

In addition, the specification was found to be objectionable in regard to the alleged utility of the method of the invention. The Examiner asserts that "[t]here is no evidence that such a method would be applicable to healthy individuals having normal bone, periodontium, or ligament....[t]he specification is totally devoid of any proof that using GF would promote bone and etc. in all (healthy or not) mammals."

Applicants have withdrawn claims 1 and 20, and amended claim 19, to limit the scope of the claimed invention to a method for promoting growth of damaged bone, periodontium, and ligament. The rejection can now be withdrawn.

The example provided in the specification at pages 10-12 directly demonstrates that application of platelet derived growth factor (PDGF) to teeth damaged by periodontal disease results in the regeneration of bone, connective tissues, and periodontium. The remaining claim 19 is directed to the application of PDGF and thus, is fully enabled.

Finally, the Examiner objected to the specification on the ground that Applicants improperly incorporated by reference the subject matter of cross-related U.S. Patent Applications. All subject matter that is essential to practice the instant invention is set forth in the specification of the current application; thus, the incorporation of subject matter from cross-related patent applications is unnecessary, and Applicants have amended the specification accordingly.

35 U.S.C. § 112, second paragraph

Claims 19 and 20 were rejected under 35 U.S.C. § 112, second paragraph, on the ground that they failed to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Claim 19 was rejected on the ground that there is no antecedent basis for the term "damaged," (line 3); claim 20 was found to be indefinite in regard to the use of the term "planning." Claim 20 has been withdrawn, and Applicants have amended claim 19 to correct the inadvertent error.

35 U.S.C. § 102 and § 103

Claims 1, 19, and 20 were rejected under 35 U.S.C. § 102(a), (b), and (e) as anticipated by, or under 35 U.S.C. § 103

as obvious, over Terranova et al. Claims 1 and 20 have been withdrawn without prejudice. The following remarks are directed to the remaining claim 19.

Terranova et al. teach a method for promoting periodontal regeneration which involves demineralization of the dentin prior to application of an endothelial cell formation stimulating agent. The method of the instant invention involves the application of compositions containing PDGF after planing of the exposed bone or peridontium. The Examiner asserts that demineralization and planing are equivalent and that "in either case the object is to clean the site before GF application." Applicants traverse this rejection.

Surface demineralization of dentin results in the removal of inorganic salts from the outermost layer of the dentin, leaving the organic layer intact. This treatment is thought to facilitate the healing of the hard/soft tissue interface by providing a suitable root surface for the attachment and subsequent growth of fibroblasts (see Terranova et al., column 2, lines 2-6; column 4, lines 12-17). Planing of the root surface removes bacterial plaque and calculus. It is well known to those skilled in the art that planing removes the complete outer portion of the root surface. Thus, in addition to the outer mineral layer, all organic matter (e.g., organic salts, protein matrix, collagen fibers, bacterial products and debris) is also removed. Terranova et al. does not teach, or even suggest, that methods other than demineralization could be used for promoting periodontal regeneration. In fact, the disclosure

of Terranova et al. emphasizes the essentiality of the demineralization step for the practice of the patented invention.

Therefore, the claimed method of the instant invention is not the same as the methods of Terranova et al.

The claims were also rejected on the ground that the invention is obvious over Terranova et al. Applicants traverse this rejection. Terranova et al. provide in vitro evidence that dentin treated with tetracycline, prior to application of fibronectin, has improved new connective tissue attachment. While Terranova et al. do suggest that PDGF might be used in the method of their invention, they provide no evidence that it would work. In addition, as discussed above, this reference neither suggests or teaches methods for periodontal regeneration which do not include the step of demineralization. This negative limitation is not within the claimed method of the instant invention.


The instant invention teaches a method for promoting the growth of damaged bone, periodontium, or ligament by first planing the bone or periodontium, and then applying compositions containing PDGF. This method does not require demineralization prior to application of the PDGF, and the example provided in the instant specification demonstrates that in vivo treatment with PDGF enhances osteogenic, cementogenic, and connective tissue responses. Prior to Applicants discovery, there was no evidence that the method of the instant invention would work. Therefore, Applicants submit that the current invention, as defined by the claim, is both novel and patentable.

In response to the Examiner's request for copies of the references cited on pages 1 and 2 of the specification together with a form PTO-1449, copies of the Information Disclosure Statement, form PTO-1449, and references cited therein which were previously submitted in regard to this application, will be sent under separate cover.

In view of the above, it is submitted that all of the claims in the application are in condition for allowance, and such action is respectfully requested. Please charge and fees to Deposit Account No. 06-1050.

Respectfully submitted,

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